the FEDERAL REGISTER, this requirement may be met by simultaneous publication of the regulation and of a notice of availability of the final statement and the record of decision, provided that the regulation becomes effective no sooner than 30 days after the date of publication.

(iii) If the subject of an EIS is an FDA action governed by specific time requirements under statute or regulations, those time requirements will be extended, if at all, only as long as necessary to permit the agency to consider or issue an EIS for the action.

(c) As described in 40 CFR 1505.3, the agency may provide for monitoring to ensure that its decisions, any mitigating measures, and other conditions are carried out.

(d) Under the conditions prescribed in 40 CFR 1502.9(c), the agency will prepare a supplement for a draft or final EIS and introduce the supplement into its administrative record.

(e)(1) The agency official to whom authority for the action is delegated in part 5 will ensure both that there is balancing of environmental impacts with the agency's objective in choosing an appropriate course of action and that the public is involved and notified of the decision, as described in paragraphs (a) through (d) of this section.

(2)(i) The director of each FDA center is responsible for preparing a draft or final EIS on actions delegated to that center by the Commissioner under subpart B of part 5 of this chapter or in which the center is a party in an administrative proceeding under part 12, 13, 14, 15, or 16 of this chapter in which a draft or final EIS is required.

(ii) The Director, Office of Regional Operations, FDA, is responsible for preparing a draft or final EIS on the destruction of articles condemned after seizure, subject to an injunction, under import detention, or under detention or recalled at agency request.

(iii) The Office of the Commissioner of Food and Drugs is responsible for preparing or assigning the task of preparing a draft or final EIS on actions not otherwise assigned in this section.

[50 FR 16656, Apr. 26, 1985, as amended at 59 FR 14364, Mar. 28, 1994]

Subpart E—Other Requirements

§ 25.50 Environmental effects abroad of major agency actions.

(a) In accordance with E.O. 12114, ''Environmental Effects Abroad of Major Federal Actions'' of January 4, 1979 (44 FR 1957, Jan. 9, 1977), the responsible agency official, in analyzing actions under his or her program, shall consider the environmental effects abroad, including whether the actions involve:

(1) Potential environmental effects on the global commons and areas outside the jurisdiction of any nation, e.g., oceans and the upper atmosphere.

(2) Potential environmental effects on a foreign nation not participating with or otherwise involved in an FDA activity.

(3) The export of products (or emissions) that in the United States are prohibited or strictly regulated because their effects on the environment create a serious public health risk.

(4) Potential environmental effects on natural and ecological resources of global importance designated under the Executive Order.

(b) Before deciding on any action falling into the categories specified in paragraph (a) of this section, the responsible agency official shall determine in accordance with section 2–3 of the Executive Order whether such actions may have a significant environmental effect abroad.

(c) If the responsible agency official determines that an action may have a significant environmental effect abroad, the responsible agency official shall determine in accordance with section 2–4(a) and (b) of the Executive Order, whether the subject action calls for:

(1) An EIS;

(2) A bilateral or multilateral environmental study; or

(3) A concise environmental review.

(d) In preparing environmental documents under this subpart, the responsible official shall:

(1) Determine, as provided in section 2–5 of the Executive Order, whether proposed actions are subject to the exemptions, exclusions, and modification in contents, timing, and availability of documents.

(2) Coordinate all communications with foreign governments concerning environmental agreements and other arrangements in implementing the Executive Order.

PART 50—PROTECTION OF HUMAN SUBJECTS

Subpart A—General Provisions

Subpart B—Informed Consent of Human Subjects

Subpart C—Protections Pertaining to Clinical Investigations Involving Prisoners as Subjects

AUTHORITY: Secs. 201, 406, 408, 409, 502, 503, 505, 506, 507, 510, 513–516, 518–520, 701, 721, 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 346, 346a, 348, 352, 353, 355, 356, 357, 360, 360c–360f, 360h–360j, 371, 379e, 381); secs. 215, 301, 351, 354–360F of the Public Health Service Act (42 U.S.C. 216, 241, 262, 263b–263n).

SOURCE: 45 FR 36390, May 30, 1980, unless otherwise noted.

Subpart A—General Provisions

§ 50.1 Scope.

(a) This part applies to all clinical investigations regulated by the Food and Drug Administration under sections 505(i), 507(d), and 520(g) of the Federal Food, Drug, and Cosmetic Act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration, including food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. Additional specific obligations and commitments of, and standards of conduct for, persons who sponsor or monitor clinical investigations involving particular test articles may also be found in other parts (e.g., parts 312 and 812). Compliance with these parts is intended to protect the rights and safety of subjects involved in investigations filed with the Food and Drug Administration pursuant to sections 406, 409, 502, 503, 505, 506, 507, 510, 513–516, 518–520, 721, and 801 of the Federal Food, Drug, and Cosmetic Act and sections 351 and 354–360F of the Public Health Service Act.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

[45 FR 36390, May 30, 1980; 46 FR 8979, Jan. 27, 1981]

§ 50.3 Definitions.

As used in this part:

(a) *Act* means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201—902, 52 Stat. 1040 *et seq.* as amended (21 U.S.C. 321—392)).

(b) *Application for research or marketing permit* includes:

(1) A color additive petition, described in part 71.

(2) A food additive petition, described in parts 171 and 571.

(3) Data and information about a substance submitted as part of the procedures for establishing that the substance is generally recognized as safe for use that results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, described in §§ 170.30 and 570.30.

(4) Data and information about a food additive submitted as part of the procedures for food additives permitted to be used on an interim basis pending additional study, described in § 180.1.

(5) Data and information about a substance submitted as part of the procedures for establishing a tolerance for unavoidable contaminants in food and